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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,178	03/03/2004	David E. Francischelli	P-8575.06	4900
27581	7590	06/23/2011		
Medtronic, Inc. (CRDM) 710 MEDTRONIC PARKWAY NE MS: LC340 Legal Patents MINNEAPOLIS, MN 55432-9924			EXAMINER JOHNSON III, HENRY M	
			ART UNIT 3769	PAPER NUMBER
			NOTIFICATION DATE 06/23/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.docketingus@medtronic.com  
medtronic\_crmd\_docketing@cardinal-ip.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/792,178	<b>Applicant(s)</b> FRANCISCHELLI ET AL.	
	<b>Examiner</b> Henry M. Johnson, III	<b>Art Unit</b> 3769	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

In view of the Appeal Brief filed on 5/13/2011, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/SAM YAO/

Supervisory Patent Examiner, Art Unit 3769.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment filed 11/01/2010 added the term "and the vibration occurs prior to substantial boiling to water in the organic tissue". This terminology is not supported by the original disclosure and is new matter. The Applicant discloses sensing vibration prior to a "steam pop", but not prior to substantial boiling.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 cites "prior to substantial boiling". The term substantial is a relative term and renders the claim indefinite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,733,281 to Nardella. Nardella discloses a method of tissue ablation comprising positioning an electrode (energy delivering electrode; Col. 4, lines 20-25, positioning is inherent for an ablation operation), supplying electrical power (electrosurgical energy; Col. 6, lines 54-55), sensing with a sensor (acoustical detection element; Col. 2, lines 46-49) the vibration of the tissue and reducing/halting ("regulating", patented claim 3; power regulation element; col. 8, lines 57-60) power when the vibration reaches a given value. The acoustic detection element may be a piezoelectric ceramic crystal (Col. 7, line 35) or a microphone (Col 3, line 4). Nardella teaches a feedback system that includes an acoustical detection element coupled to the surgical tool and the pulse regulation element for acoustically detecting the effects of energy on tissue, such as the generation of steam created during the heating process. The acoustical detection element preferably generates an acoustic output signal, and the power regulation element preferably regulates the application of power to the energy-delivering electrode in response to either the derivative output signal or the acoustic output signal (Col. 2, lines 46-51).

Nardella, however, does not specifically disclose reducing power prior to substantial boiling. Nardella is concerned with the destructive effects of steam during tissue ablation and associates steam and "pops" with steam buildup that may lead cells to explode (Col. 1, lines 25-48). Nardella teaches adjusting the acoustic (vibration) feedback to regulate the relative levels of steam to within a selected range, and preferably below that level that may cause permanent and/or unwanted damage to the

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tissue (Col. 6, lines 42-46). It is the examiner's position that one of skill in the art, aware of such serious issues, would associate both boiling and steam pops as indicative of excessive energy. Nardella specifically teaches that the term "acoustic" is intended to include any vibratory disturbance of any frequency in a selected fluid, such as air, and includes sonic and ultrasonic waves (Col. 2, lines 46-59).

Regarding claim 27, Nardella incorporates by reference in Col. 9, line 56, Nardella (5,334,193), which discloses impedance feedback control of fluid delivery to treated tissue (see '193 Abstract).

Regarding claims 29 and 30, Nardella discloses an output device (Analyzer, Fig. 2, # 130) and an indicator signal (Fig. 2, # 132, signal to RF generator).

Regarding claim 32, PVDF is a piezoelectric polymer (Col. 7, line 36).

Regarding claim 33, sensor (Fig. 2, # 20) is integrated with the electrode (Fig. 2, # 12).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571)272-4768. The examiner can normally be reached on M-F, 6 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam C. Yao can be reached on 571.272.1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Henry M. Johnson, III/  
Primary Examiner, Art Unit 3769

June 15, 2011